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10 February 2003

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INTERNATIONAL PATENT LAW DIVISION

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Please quote our ref. in reply OUR REF MJ/JN/rma/PAT/8103549/SG

YOUR RIE JJM0478

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Dear Sirs.

Singapore Patent Application No. 200007567-1

Applicant:

ETHICON, INC.

Invention:

SAFETY CATHETER WITH TORTUOUS FLUID PATH

The Examiner has issued a Written Opinion on the Search and Examination Report, a copy of w enclosed for your retention.

The Examiner has found Claim 6 not novel and Claims 1-13 lack inventive step. He has identified six cited references namely, US5743882, US4828547, US5312345, US5951520, EP630661 and EP353905 to be relevant to this application. However, he stated that these references were found in the International Search Report, which should not be the case, as this was not a PCT application. Further, no cited documents were given to us. In this regard, we will write to the Registrar to clarify on this discrepancy.

The Examiner has made some observations in relation to the clarity of the present application as follows:

- 1. In Claim 1, it is not clear what is represented by the member in line 5 which reads "a member at the proximal...". Further, the working interrelationship between (a) flash chamber and safety member and (b) the porous member seated within a member is not clear.
- 2. Claims I and 9 are not fully supported by the description because each of the claims omits the feature of blunting member being axially movable from a non-blunting position and a blunting position, Claim 9 is particularly speculative as it omits several essential features related to the functional relationship of the device. It is not clear whether the blunting member is inside/outside the needle. Coaxial or otherwise? Movable or fixed?
- 3. In Claim 6, it is not clear if the blunt distal tip of the blunting member is merely blunt or is it blunt and closed at the end. The term "an opened proximal end" followed by "a blunt distal tip" implies closed end.

2/...

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Chief Operating Officer Joseph Kon

Senior Consultant
J Grimherg,
Senior County

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Page 2

DREW & NAPIER LLC

Our ref.: MJ/JN/rma/PAT/8103549/SG

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Your ref.: JJM0478

Date: 10 February 2003

4. Claim 7 repeats the feature of a lumen, which extends longitudinally through the blunting member.

- 5. Claims 8 and 13 are not clear because the terms "porous member" und "flash chamber" have no clear prior reference.
- 6. Claim 6 is not supported by the description because it omits a removable porous stopper. This feature appears to be essential when the specification is read as a whole because without the porous stopper, the escape of blood or other bodily fluid during use cannot be prevented.

Should you wish to file any arguments/amendments in response to the said Opinion, please let us have your instructions at least two weeks before the non-extendable deadline of 14 June 2003 (five months from the date of the Registrar of Patents' letter). We would appreciate if you could send us the replacement pages for all amendments to be made to the description, claims, abstract and drawings, so that we may expedite the preparation of a response to the Intellectual Property Office of Singapore.

Alternatively, we would be pleased to assist you to prepare a substantive response to the Written Opinion. Please note, however, that we will require at least eight weeks to review the specifications in detail, seek your technical input, draft a response and seek your approval. Should you wish us to do so, please let us have your instructions by 19 April 2003 and an indication as to the novel features of your invention. In the absence of your instructions by 19 April 2003, we will assume that you do not require us to prepare a substantive response and that you will forward to us a response prepared at your end (if any).

Please note that if you choose not to respond to the said Opinion, the final Examination Report will be established on the basis of the said Written Opinion. In this regard, should you wish to file voluntary amendments after the final Examination Report is issued and before the fee for grant is paid, the amendments will not subject to further examination. For your information, an unfavourable Examination report will militance the opinion but will not be binding on the court in the event of revocation proceedings commenced by a target party.

We look forward to receiving your instructions soon.

Yours faithfully,

Enc.

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Registry of Patents Intellectual Property Office of Singapore

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In Reply Please Quote Our Reference

Your Ref

: MZ/Z~/ma/PAT/8103549/2G

Our Ref

200007567-1

Date

14/01/03

Writer's Direct Line:

£ 330 2748

Drew & Napier Robinson Road P O Box 152 Singapore 900302

Dear Sirs.

Invitation To Respond To A Written Opinion			
Application No:	200007567-1	(
Applicant:	EtRicon Inc		
Request Filed On:	16/07/01		

Attached is a copy of written opinion drawn up by the Examiner in connection with the request made for:

Q/

Search and Examination Report; or

Examination Report

You are invited to respond to this opinion by submitting:

- (a) written arguments disagreeing with the Examiner's opinion, and/or
- (b) an amendment of the specification of the application.

If you intend to respond, the response must be filed within <u>5 months</u> from the date of this letter. You are also advised to let us know early by completing Part II of this letter if you intend not to respond.

The examiner will proceed to establish the examination report at the expiration of the allowed period when no response is received.

Og

Annle Besant d/o Surendran (Madam) for Registrar of Patents Singapore

Part II

We refer to the above invitation. We do not wish to respond to this written opinion and please inform the IP, Australia / Austrian Patent Office ** accordingly. . .

Date

• • delete as appropriate

Name of Agent

A statutory board of the Ministry of Law

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AUSTRALIAN PATENT OFFICE

WRITTEN OPINION

		Date of mailing day/month/year 2.2 NOV 2002		
Applicant's or agent's file reference MJ/JN/rma/PAT/8103549/SG		REPLY DUE within FIVE MONTHS of the date of the Registrar's letter enclosing the written opinion		
Application No.	Application Filing Date (day/month/year)		Priority Date (day/month/year)	
SG 200007567-1	20 December 2000		21 December 1999	
International Patent Classification (IPC) (as indicated in the search report) Int. Cl. 7 A61M 25/06				
Applicant ETHICON, INC.				
1. This First written opinion consists of a	total of 4 sheets.			
2. This opinion contains indications relating	g to the following iten	ms:.		
I X Basis of the opinion				
II Non-establishment of opi	nion with regard to no	ovelty, inventive step a	nd industrial applicability	
III Lack of unity of invention	1			
	IV Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			
V Certain documents cited				
VI Certain defects in the app	lication			
VII X Certain observations on the	ne application			
3. This opinion is based upon the assumption	. This opinion is based upon the assumption that the priority claim is valid.			
4. The search report used was issued by the	Australian Patent	Office, and the date o	f completion is: 19 September 2002	
5. If no reply is filed, the examination report	5. If no reply is filed, the examination report will be established on the basis of this opinion.			
6. The date by which the examination repor	t will be established i	s: 21 March 2004		
Name and mailing address		Authorized Officer		
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Fuesimile no. 61 2 62853929		Mr. SWAYAM C	HINTAMANI .	

Form APO/SG/408 (Cover Sheet)(Feb 2000)

AUSTRALIAN PATENT OFFICE WRITTEN OPINION

MACHOLI & BULLETA . UNER & MAFTER LLL

Application No.
SG 200007567-1

1.	Basis of the opin	ion
1.	This opinion has been	drawn on the basis of:
	X the application a	as originally filed.
	the description,	pages , as originally filed,
		pages , filed with the request,
		pages , received on with the letter of
	the claims,	pages , as originally filed,
		pages , filed with the request,
	<u>_</u>	pages , received on with the letter of
!	the drawings,	sheets/fig. , as originally filed,
		sheets/fig. , filed with the request,
		sheets/fig. , received on with the letters of
	the sequence list	ting part of the description:
		pages , as originally filed
		pages , filed with the demand
		pages , received on with the letter of
2.	The amendments have	resulted in the cancellation of: pages:
		sheets of drawings/figures No:
3	This opinion has go beyond the di	been established as if (some of) the amendments had not been made, since they have been considered to sclosure as filed, as indicated in the Supplemental Box.
4.	Additional observation	s, if necessary:

AUSTRALIAN PATENT OFFICE

WRITTEN OPINION

Application No.

SG 200007567-1

IV. Reasoned statement under with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1			
1.	1. Statement		
	Novelty (N)	Claims 1-5, 7-13	YES
		Claims 6	МО
	Inventive step (IS)	Claims	YES
		Claims 1-13	NO
	Industrial applicability (IA)	Claims 1-13	YES
		Claims	NO

2. Citations and explanations

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 US 5743882

D2 US 4828547 -

— D3 US 5312345—

— D4 US 5951520-

D5 EP 630661 ✓

D6 EP 353905 √

Novelty (N) Claims 1-13

Claims 6 is not novel when compared to each one of D1-D4. Nove aments cited above disclose the use of a removable porous stopper at the end of a flash chamber. But, since this feature is not a part of all the claims, the feature appears to be optional. Barring this optional feature, each of the documents cited above discloses all the essential features of each of the independent claims.

Inventive Step (IS) claims 1-13

Claim 6 is not inventive for the reasons stated above. Claims 1-5 and 7-13 are not inventive because the use of a porous removable stopper at the end appears to be an obvious design choice for preventing exposure if the end is open.

1

AUSTRALIAN PATENT OFFICE WRITTEN OPINION

Application No. SG 200007567-1

VII. Certain observations on the application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

- 1. In claim 1 it is not clear what is represented by the member in line 5 which reads "a member at the proximal..". Further, the working interrelationship between (a) flash chamber and safety member and (b) the porous member seated within a member is not clear.
- 2. Claim 1 and 9 are not fully supported by the description because each of the claims omits the feature of blunting member being axially movable from a non-blunting position and a blunting position.

Claim 9 is particularly speculative as it omits several essential features related to the functional relationship of the device. It is not clear whether the blunting member is inside/outside the needle. Coaxial or otherwise? Moveable or fixed?

- 3. In claim 6 it is not clear if the blunt distal tip of the blunting member is merely blunt or is it blunt and closed at the end. The term "an opened proximal end" followed by "a blunt distal tip" implies closed end.
- 4. Claim 7 repeats the scature of a lumen, which extends longitudinally through the blunting member.
- 5. Claims 8 and 13 are not clear because the terms "porous member" and "flash chamber" have no clear prior reference.
- 6. Claim 6 is not supported by the description because it omits a removable porous stopper. This feature appears to be essential when the specification is read as a whole because without the porous stopper, the escape of blood or other bodily fluid during use cannot be prevented.

The claimed invention is patentable according to Section 13(3); or
The claimed invention is unpatentable according to Section 13(3), because:

Form APO/SG/408 (Box VII)(Fcb 2000)

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